

# **EXHIBIT F**

**(Brief in Support of Plaintiffs' Motion to Stay)**



## UNITED STATES PATENT AND TRADEMARK OFFICE

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## NOTICE OF ALLOWANCE AND FEE(S) DUE

23416 7590 01/06/2009

CONNOLLY BOVE LODGE & HUTZ, LLP  
 P O BOX 2207  
 WILMINGTON, DE 19899

EXAMINER

KOSACK, JOSEPH R

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 01/06/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/653,830	01/16/2007	Bruce D. Roth	00121-00478-USRE	5953
TITLE OF INVENTION: [R-(R*R*)]-2-(4-FLUOROPHENYL)-BETA,DELTA-DIHYDROXY-5-(1-METHYLETHYL-3-PHENYL-4-[PHENYLAMINO]CARBONYL)-1H-PYRROLE-1-HEPTANOIC ACID, ITS LACTONE FORM AND SALTS THEREOF				

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$0	\$0	\$1510	04/06/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

## HOW TO REPLY TO THIS NOTICE:

## I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

## PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 or Fax (571) 273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

23416 7590 01/06/2009

CONNOLLY BOVE LODGE & HUTZ, LLP  
 P O BOX 2207  
 WILMINGTON, DE 19899

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

## Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/653,830	01/16/2007	Bruce D. Roth	00121-00478-USRE	5953
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TITLE OF INVENTION: [R-(R\*R\*)]-2-(4-FLUOROPHENYL)-BETA,DELTA-DIHYDROXY-5-(1-METHYLETHYL-3-PHENYL-4-[PHENYLAMINO]CARBONYL)-1H-PYRROLE-1-HEPTANOIC ACID, ITS LACTONE FORM AND SALTS THEREOF

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$0	\$0	\$1510	04/06/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
KOSACK, JOSEPH R	1626	514-422000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).	2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
<input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.	1. _____
<input type="checkbox"/> "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.	2. _____
	3. _____

## 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent):  Individual  Corporation or other private group entity  Government

4a. The following fee(s) are submitted:	4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)
<input type="checkbox"/> Issue Fee	<input type="checkbox"/> A check is enclosed.
<input type="checkbox"/> Publication Fee (No small entity discount permitted)	<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.
<input type="checkbox"/> Advance Order - # of Copies _____	<input type="checkbox"/> The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)	<input type="checkbox"/> a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.	<input type="checkbox"/> b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).
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NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_

Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Registration No. \_\_\_\_\_

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
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11/653,830	01/16/2007	Bruce D. Roth	00121-00478-USRE	5953		
23416	7590	01/06/2009	EXAMINER			
<b>CONNOLLY BOVE LODGE &amp; HUTZ, LLP</b> <b>P O BOX 2207</b> <b>WILMINGTON, DE 19899</b>				KOSACK, JOSEPH R		
		ART UNIT		PAPER NUMBER		
				1626		
DATE MAILED: 01/06/2009						

**Determination of Patent Term Extension or Adjustment under 35 U.S.C. 154 (b)**

A reissue patent is for "the unexpired part of the term of the original patent." See 35 U.S.C. 251. Accordingly, the above-identified reissue application is not eligible for Patent Term Extension or Adjustment under 35 U.S.C. 154(b).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

<b>Notice of Allowability</b>	Application No.	Applicant(s)
	11/653,830	ROTH, BRUCE D.
	Examiner Joseph R. Kosack	Art Unit 1626

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 18 September 2008.
2.  The allowed claim(s) is/are 6,13 and 14.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 6/10/08 & 6/27/08
4.  Examiner's Comment Regarding Requirement for Deposit of Biological Material
5.  Notice of Informal Patent Application
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

Application/Control Number: 11/653,830  
Art Unit: 1626

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#### **DETAILED ACTION**

Claims 6, 13, and 14 are pending in the instant application.

The patent sought to be reissued by this application is involved in litigation. Any documents and/or materials which would be material to the patentability of this reissue application are required to be made of record in reply to this action.

Due to the related litigation status of this application, EXTENSIONS OF TIME UNDER THE PROVISIONS OF 37 CFR 1.136(a) WILL NOT BE PERMITTED DURING THE PROSECUTION OF THIS APPLICATION.

A shortened statutory period for reply is set to expire 1 month(s) or thirty (30) days, whichever is longer, from the mailing date of this communication.

#### ***Amendments***

The amendment filed on June 10, 2008 is acknowledged and is entered into the application file.

The claim listing filed on September 18, 2008 is acknowledged and is compliant with 37 CFR 1.173(b) and is entered into the instant application file.

#### ***Information Disclosure Statement***

The Information Disclosure Statements filed on June 10, 2008 and June 27, 2008 have been considered by the Examiner.

#### ***Previous Specification Objections***

The specification was previously objected to for not containing a valid cross reference to other reissue applications filed for USPN 5,273,995. The cross reference

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was inserted in the amendment filed on June 10, 2008 as suggested by the Examiner and the objection is withdrawn.

***Previous Claim Rejections - 35 USC § 103***

Claims 6, 13 and 14 were previously rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,681,893 in view of Berge et al.

Applicant has traversed the rejection on the grounds that the objective evidence of secondary considerations, such as unexpected results, commercial success, long felt need, and copying, outweigh the *prima facie* case of obviousness set forth by the Office.

Applicant has submitted 37 CFR 1.132 declarations by Dr. William Sasiela, Dr. Peter Jones, Chris Bokhart, Eugene Kolassa, Michael Suesserman, and James Thomas Sage in support of the traversal.

The arguments have been persuasive for the following reasons. Firstly, the Bokhart declaration clearly shows that the commercial success of atorvastatin calcium (marketed as LIPITOR) was not due to an excessive amount of advertising and promotion as compared to the competitors previously in the marketplace for statin drugs. Atorvastatin calcium was the fifth entry into the marketplace and enjoyed commercial success far beyond the projections made by Pfizer given the amount spent on advertising and promotions during the launch in 1997. Therefore, it can be concluded that the high level of commercial success shown by atorvastatin calcium in the marketplace can be attributed to the medical properties of the claimed subject matter and not by any extraneous factors such as excessive advertising and promotion.

Application/Control Number: 11/653,830  
Art Unit: 1626

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While evidence of long felt need and copying is presented in the declarations and arguments, they have not been found to be persuasive for the following reasons. The long felt need was at least met in part by previous statins in order to help high risk patients meet their LDL goals. Additionally, the copying of a drug for an ANDA is an extremely common practice for generic drug companies under the Hatch-Waxman act in order to attempt to obtain a six month exclusive right to market the generic form of a drug after the expiration of the patent(s) covering the drug. Therefore, copying for an ANDA is not necessarily a sign that the generic company has failed to develop their own statin, but is a possible strategy to compete in the generic marketplace upon expiration of a patented drug's patent term.

However, the evidence of the unprecedented commercial and medical success of atorvastatin calcium that can be attributed to the claimed drug and not to any extraneous factors such as excessive advertising and promotion outweighs the *prima facie* case of obviousness set forth previously by the Office. Therefore, one of skill in the art would deem the claims to be non-obvious. The rejection is withdrawn.

#### ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance: the differences between the claimed invention and the closest prior art of Roth (USPN 4,681,893) is that a particular stereoisomer of the racemate is used along with a particular salt form of the stereoisomer. While a *prima facie* case of obviousness can be made over Roth in view of Berge et al., which teaches various FDA approved pharmaceutical salts, the case is overcome base on the objective evidence presented

Application/Control Number: 11/653,830  
Art Unit: 1626

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by the Applicant of unexpected medical and commercial success of the claimed atorvastatin calcium that is not under the influence of extraneous factors such as excessive advertising and promotion. Therefore, claims 6, 13, and 14 are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

Claims 6, 13, and 14 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph R Kosack/  
Examiner, Art Unit 1626

/Joseph K. McKane/  
Supervisory Patent Examiner, Art Unit 1626

# **EXHIBIT G**

**(Brief in Support of Plaintiffs' Motion to Stay)**

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND	:
PHARMACEUTICALS, WARNER-	:
LAMBERT COMPANY, WARNER-	:
LAMBERT COMPANY, LLC, and	:
WARNER-LAMBERT EXPORT, LTD.,	:
	:
Plaintiffs,	:
	:
v.	:
	Civil Action No. 03-209-JJF
	(Consolidated)
RANBAXY LABORATORIES LIMITED	:
and RANBAXY PHARMACEUTICALS,	:
INC.,	:
	:
Defendants.	:

O R D E R

WHEREAS, by Order dated November 7, 2006, the Court modified the Final Judgment Order entered on January 4, 2006, in light of the decision by the Court of Appeals for the Federal Circuit that United States Patent No. 5, 273, 995 (the "'995 patent) is invalid;

WHEREAS, it has come to the Court's attention that further modification of the Final Judgment Order is required;

WHEREAS, because the '995 patent has been declared invalid, a basis no longer exists to support delaying the approval of Ranbaxy's Abbreviated New Drug Application No. 76-477 ("ANDA");

NOW THEREFORE, IT IS FURTHER ORDERED that the sixth paragraph of the Final Judgment Order delaying the effective date

Case 1:03-cv-00209-JJF Document 344 Filed 11/30/2006 Page 2 of 2

of any approval of Ranbaxy's ANDA until a date not earlier than  
the expiration of the '995 patent is STRICKEN.

November 30 2006  
DATE

Joseph J. Farrow  
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

PFIZER INC, PFIZER IRELAND	)	
PHARMACEUTICALS, WARNER-LAMBERT	)	
COMPANY, WARNER-LAMBERT COMPANY,	)	
LLC and WARNER-LAMBERT EXPORT, LTD.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 03-209-JJF
	)	(Consolidated)
RANBAXY LABORATORIES LIMITED, and	)	
RANBAXY PHARMACEUTICALS	)	
INCORPORATED,	)	
	)	
Defendants.	)	

**FINAL JUDGMENT ORDER**

This action having come to trial before the Court, Honorable Joseph J. Farnan, Jr., District Judge presiding; the issues having been heard and a decision having been rendered:

**IT IS ORDERED AND ADJUDGED** this 3rd day of January, 2006, for the reasons set forth in the Court's Memorandum Opinion dated December 16, 2005, that Judgment shall be entered in favor of plaintiffs Pfizer Inc, Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company LLC and Warner-Lambert Export, Ltd. (collectively "Pfizer") and against defendants Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Incorporated (collectively "Ranbaxy") on Pfizer's claims that Ranbaxy has infringed claims 1-4, and 8-9 of United States Patent No. 4,681,893 (the "'893 Patent") and claim 6 of United States Patent No. 5,273,995 (the "'995 Patent"); and it is further,

**ORDERED AND ADJUDGED** that Judgment shall be entered in favor of Pfizer and against Ranbaxy on all counterclaims alleging noninfringement, invalidity, or unenforceability of the '893 Patent or its patent term extension; and it is further,

**ORDERED AND ADJUDGED** that Judgment shall be entered in favor of Pfizer and against Ranbaxy on all counterclaims alleging noninfringement, invalidity, or unenforceability of the '995 Patent; and it is further,

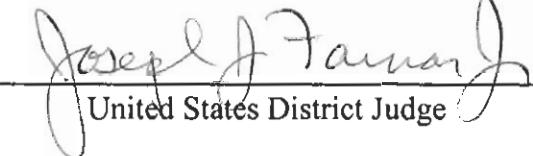
**ORDERED** that pursuant to 35 U.S.C. § 271 (e) (4) (A), the effective date of any approval of Ranbaxy's Abbreviated New Drug Application No. 76-477 shall be a date which is not earlier than the date of expiration of the '893 Patent and its patent term extension (September 24, 2009, with attached six months of pediatric exclusivity ending on March 24, 2010, to which Pfizer is entitled); and it is further,

**ORDERED** that pursuant to 35 U.S.C. § 271 (e) (4) (A), the effective date of any approval of Ranbaxy's Abbreviated New Drug Application No. 76-477 shall be a date which is not earlier than the date of expiration of the '995 Patent (December 28, 2010, with attached six months of pediatric exclusivity ending on June 28, 2011, to which Pfizer is entitled); and it is further,

**ORDERED** that pursuant to 35 U.S.C. § 271 (e) (4) (B), defendants Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Incorporated, each of their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them or either of them are permanently enjoined from engaging in the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any product comprising atorvastatin calcium covered by, or the use of which is covered by claims 1-4 and 8-9 of the '893 Patent; and it is further,

**ORDERED** that pursuant to 35 U.S.C. § 271 (e) (4) (B), defendants Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Incorporated, each of their officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them

or either of them are permanently enjoined from engaging in the manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any product comprising atorvastatin calcium covered by, or the use of which is covered by claim 6 of the '995 Patent.

  
\_\_\_\_\_  
United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND :  
PHARMACEUTICALS, WARNER- :  
LAMBERT COMPANY, WARNER- :  
LAMBERT COMPANY, LLC, and :  
WARNER-LAMBERT EXPORT, LTD., :  
:  
Plaintiffs, :  
:  
v. : Civil Action No. 03-209-JJF  
: (Consolidated)  
RANBAXY LABORATORIES LIMITED :  
and RANBAXY PHARMACEUTICALS, :  
INC., :  
:  
Defendants. :  
:

O R D E R

WHEREAS, the Court of Appeals for the Federal Circuit has issued its decision in the above-captioned appeal, affirming-in-part, reversing-in-part, and remanding this matter for modification of the permanent injunction; Pfizer Inc. v. Ranbaxy Laboratories Ltd., 457 F.3d 1284 (Fed. Cir. 2006);

WHEREAS, specifically, the Federal Circuit concluded that United States Patent No. 5,273,995 (the "'995 patent") was invalid for failure to comply with the requirements of 35 U.S.C. § 112, ¶ 4;

NOW THEREFORE, IT IS HEREBY ORDERED that, consistent with the Federal Circuit's decision, the last paragraph of the Final Judgment Order dated January 3, 2006, and entered by the Court on January 4, 2006, enjoining Defendants and others "from engaging in the manufacture, use, offer to sell, or sale within the United

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States, or importation into the United States, of any product comprising atorvastatin calcium covered by, or the use of which is covered by claim 6 of the '995 Patent" is STRICKEN.

November 7, 2006

DATE

  
UNITED STATES DISTRICT JUDGE

# **EXHIBIT H**

**(Brief in Support of Plaintiffs' Motion to Stay)**



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
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[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/653,830	03/17/2009	RE40667	00121-00478-USRE	5953

23416            7590            02/25/2009  
**CONNOLLY BOVE LODGE & HUTZ, LLP**  
 P O BOX 2207  
 WILMINGTON, DE 19899

### ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

#### **Determination of Patent Term Extension or Adjustment under 35 U.S.C. 154 (b)**

A reissue patent is for "the unexpired part of the term of the original patent." See 35 U.S.C. 251. Accordingly, the above-identified reissue application is not eligible for Patent Term Extension or Adjustment under 35 U.S.C. 154(b).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (571)-272-4200.

**APPLICANT(s)** (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Bruce D. Roth, Ann Arbor, MI;

# **EXHIBIT I**

**(Brief in Support of Plaintiffs' Motion to Stay)**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

PFIZER INC, )  
PFIZER IRELAND PHARMACEUTICALS, )  
WARNER-LAMBERT COMPANY, )  
WARNER-LAMBERT COMPANY, LLC )  
and WARNER-LAMBERT EXPORT LTD., )  
Plaintiffs/Counterclaim-Defendants )  
v. )  
COBALT PHARMACEUTICALS, INC., )  
Defendant/Counterclaim-Plaintiff. )  
C.A. No.07-790-JJF

**CONSENT JUDGMENT AND ORDER OF COURT**

WHEREAS, plaintiffs/counterclaim defendants Pfizer Inc, Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC and Warner-Lambert Export Ltd. ("Pfizer"), and defendant-counterclaim plaintiff Cobalt Pharmaceuticals Inc. ("Cobalt") stipulate that:

1. Cobalt admits that U.S. Patent No. 5,273,995 ("the '995 patent") would be infringed by the commercial manufacture, use, offer to sell or sale within the United States or importation or causing, directly or indirectly, the importation into the United States the proposed product that is the subject of Cobalt's New Drug Application ("NDA") 22-245, comprising atorvastatin sodium.
2. Cobalt admits that U.S. Patent No. 5,273,995 is valid and enforceable and waives its defenses and counterclaims in the above-captioned action.

3. Any Protective Order entered by the Court in this action shall remain in full force and effect notwithstanding this Judgment and Order.
4. The parties waive any right of appeal from this Judgment and Order.
5. Each party shall bear its own costs, expenses and attorneys' fees in connection with this action.

NOW THEREFORE, IT IS ORDERED AND ADJUDGED, on consent of the parties, that judgment shall be entered in favor of plaintiffs Pfizer Inc, Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, Warner-Lambert Company, LLC and Warner-Lambert Export Ltd. and against defendant Cobalt Pharmaceuticals Inc that Cobalt has infringed United States Patent No. 5,273,995; and it is further

ORDERED AND ADJUDGED that judgment shall be entered in favor of Pfizer and against Cobalt, dismissing all counterclaims alleging and seeking declarations of non-infringement, invalidity or unenforceability of the '995 patent; and it is further

ORDERED that, pursuant to the provisions of 35 U.S.C. §271(e)(4)(A), the effective date of any approval of Cobalt's NDA 22-245, seeking FDA approval of atorvastatin sodium tablets, 10, 20, 40 and 80 mg dosage strengths, shall be a date which is not earlier than the date of expiration of the '995 patent (December 28, 2010); and it is further,

ORDERED that, pursuant to the provisions of 35 U.S.C. §271(e)(4)(B), Cobalt, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with Cobalt are enjoined until the date of expiration of the '995 patent (December 28, 2010) from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any product comprising the chemical

compound atorvastatin sodium covered by, or the sale or use of which is covered by, the '995 patent.

Dated: May 14, 2008

CONNOLLY BOVE LODGE & HUTZ

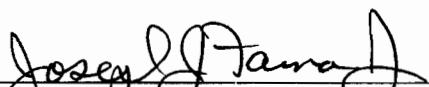
By: /s/ Jeffrey B. Bove  
Rudolf E. Hutz (#484)  
Jeffrey B. Bove (#998)  
Mary W. Bourke (#2356)  
The Nemours Building  
1007 North Orange Street  
Wilmington, DE 19899  
(302)-658-9141  
rhutz@cblh.com  
*Attorneys for Plaintiffs Pfizer Inc,  
Pfizer Ireland Pharmaceuticals,  
Warner-Lambert Company, Warner-  
Lambert Company, LLC and Warner-  
Lambert Export Ltd.*

Dated: May 14, 2008

YOUNG CONAWAY STARGATT &  
TAYLOR, LLP

By: /s/ Jeffrey T. Castellano  
John Shaw (#3362)  
Jeffrey T. Castellano (#4837)  
The Brandywine Building  
1000 West Street, 17<sup>th</sup> Floor  
Wilmington DE 19899  
(302)-571-6600  
jshaw@ycst.com  
jcastellano@ycst.com  
*Attorneys for Defendant Cobalt  
Pharmaceuticals, Inc.*

IT IS SO ORDERED, this 15 day of May, 2008.

  
The Honorable Joseph J. Farnan, Jr.  
United States District Judge